CATHOLIC HEALTH INITIATIVES

St. Joseph Medical Center

May 25, 2007

SENT VIA FAX

David A. Neumann, Ph.D.,
Health Policy Analyst
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 12215

Re: COMAR 10.25.05 – Informal Comment on Draft Regulations

Dear Dr. Neumann:

St. Joseph Medical Center remains opposed to any waiver of the existing co-location requirement for elective (non-primary) PCI and open heart surgery in Maryland's State Health Plan. We are nonetheless taking this opportunity to provide informal comment to the above referenced Draft Regulations.

10.24.05.02.C The Commission may grant a waiver from Policy 5.0 of COMAR 10.24.17.04E for no more than six (6) hospitals without on-site cardiac surgery to perform non-primary PCI as part of the C-Port study.

St. Joseph Medical Center is in the midst of a $100 million capital investment, a project that includes a significant expansion of existing capacity to provide PCI. The Commission should strongly consider that any additional hospitals providing non-primary PCI will have a direct, negative impact on volumes at existing cardiac surgery centers in Maryland. No more than 1 hospital per planning region should be considered for inclusion in any study of non-primary PCI absent cardiac surgery back-up.

10.24.05.04.A(2)(b) Physician Resources. An application must document that it has or will recruit adequate staff necessary for the provision of primary and non-primary PCI services, including a minimum of three interventional cardiologists

The Commission should require at least 4 interventionalist for any hospital seeking to provide non-primary PCI under the C-Port study. Experience suggests 4-5 interventionalist are necessary to provide 24/7 coverage in the cath lab. The Commission should also consider the negative impact to existing Maryland cardiac surgery centers. Not only are interventionalists extremely difficult to recruit, but a continuing crisis in staffing the cath lab with the appropriate techs and RNs remains a daily, operational challenge. Duplicating Maryland's current capacity will only generate a bidding war for physicians and staff in our cath labs.

10.24.05.04.A(2)(c) Review of Applications. Minimum Volumes. An applicant must document that it will meet and maintain a minimum volume of 200 PCI procedures annually.

It is unclear whether the draft regulations require a minimum of 200 non-primary PCI annually, or a minimum of 200 primary and non-primary PCI collectively in a year. The Commission should determine separate minimum volume criteria for primary and non-primary PCI. St. Joseph would argue that the volume criteria for non-primary PCI should be much higher than 200 cases annually. In practice this translates to less than 1 intervention a day. If not cost prohibitive to a Maryland hospital to maintain a non-primary PCI program with volumes at or near 200 cases annually, it should be rejected under any health planning tenet seeking the rational allocation of scarce resources, including physician, staff and capital.

10.24.05.04.A(3) In determining whether to grant a waiver application, the Commission may consider appropriate factors, including:

(a) An applicant's potential to improve the geographic distribution of cardiovascular services;

(b) An applicant's potential to increase access to PCI services for minorities and medically underserved populations;

(c) An applicant's ability to serve as a site for conducting research;

(d) An applicant's demonstration of successful and timely acquisition of follow-up data on primary PCI patients; and

(e) An applicant's current performance under its primary PCI waiver.

The Commission should be **required** to consider all of the above factors in granting a waiver to perform non-primary PCI. Additionally, the Commission should be required to consider whether granting a non-primary PCI waiver will:

(1) have an adverse impact on existing Maryland cardiac surgery centers;
(2) increase costs to the health care delivery system in Maryland; and
(3) further mitigate staffing shortages at existing Maryland cardiac surgery centers.

Maryland's cardiac provider network is fundamentally sound, and supports the objectives to:

- Produce high volume Centers of Excellence for the treatment of cardiovascular disease
- Create and support highly experienced staff and cardiac teams at our Centers
- Maintain high quality programs, and
- Promote rational allocation of limited health care resources.

Adding unnecessary and duplicative capacity under a non-primary PCI waiver will:

- Add real costs to Maryland's health care delivery system
- Dilute volumes at existing programs
- Weaken staff support and expertise at Maryland's existing cardiac surgery programs, and
- Compromise the quality of care currently provided.

Thank you for the opportunity to comment on the Draft Regulations.

Sincerely,

Sean P. Flanagan
Director, Government Relations